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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,504	01/27/2004	Eddie F. Ray III	03190.000100.	3501
5514	7590	01/21/2009	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112				HARVEY, JULIANNA NANCY
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,504	RAY ET AL.	
	Examiner	Art Unit	
	Julianna N. Harvey	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 04 December 2008.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-66 is/are pending in the application.
 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-4,6,7,12,13,15,20,23,26,28,31-35,37,38,43,44,51,54,57,65 and 66 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 27 January 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>4 Dec. 2008</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 5,8-11,14,16-19,21,22,24,25,27,29,30,36,39-42,45-50,52,53,55,56 and 58-64.

DETAILED ACTION

Claim Objections

The objection to claims 26 and 57, as stated in the 30 May 2008 Office Action, have been withdrawn due to Applicant's amendments to these claims.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Applicant is advised that should claims 32-35, 37, 38, 43, 44, 51, 54, 57, and/or 66 be found allowable, claims 1-4, 6, 7, 12, 13, 20, 23, 26, and/or 65 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same

thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. In the present case, the only difference is the use of the word "closely" in claims 1-4, 6, 7, 12, 13, 20, 23, 26, and 65. The term "closely" is not defined by the claim nor does the specification provide a standard for ascertaining the requisite degree. As such, there is no indication that the scope of claims 1-4, 6, 7, 12, 13, 20, 23, 26, and 65 is any different than that of claims 32-35, 37, 38, 43, 44, 51, 54, 57, and 66. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6, 7, 12, 13, 15, 20, 23, 26, 28, 31, and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "closely" in claims 1-4, 6, 7, 20, 23, 28, 31, and 65 is a relative term which renders the claims, and therefore any claims depending from these claims, indefinite. The term "closely" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention because one cannot determine the amount of spacing between the protrusions based on information provided in the application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 13, 15, 20, 23, 28, 31-35, 44, 51, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntyre (US 4,950,296 A) in view of Brantigan (US 4,834,757 A). McIntyre discloses a textured bone allograft (figures 3 and 4; column 3, lines 5-36) comprising a shell ("28" in figures 3 and 4) and a block ("32" in figures 3 and 4). McIntyre fails to teach a plurality of spaced protrusions or any characteristics of those protrusions. Brantigan teaches a prosthetic fusion implant ("11" in figure 7) comprising a plurality of spaced protrusions ("22" in figure 7). Regarding claims 1 and 32, each protrusion comprises a triangular shaped cross-section (column 6, lines 40-50). Regarding claims 2, 4, 33, and 35, the plurality of protrusions comprise a plurality of spaced discrete protrusions (column 6, lines 40-50). Regarding claims 3 and 34, the protrusions are provided on one or more surfaces of the implant (figure 7). Regarding claims 13 and 44, the protrusions are provided on at least one entire cut surface of the implant (figure 7). Regarding claim 15, the protrusions are perpendicular to the surface of the implant (figure 7; column 6, lines 40-50). Regarding claims 20, 28, and 51, the protrusions are formed by a plurality of teeth ("22" in figure 7). Regarding claims 23, 31, and 54, the protrusions provide a roughened surface (column 6, lines 40-50). With regard to claims 23, 31, and 54, it is noted that the protrusions of Brantigan

appear to be substantially identical to the claimed protrusions, and as such, the process by which they are formed is irrelevant. The burden is upon applicant to come forward with evidence establishing an unobvious difference between the two. *In re Marosi*, 218 USPQ 289 (Fed. Cir. 1983). It would have been obvious to one of ordinary skill in the art at the time the invention was made to roughen at least the upper surface of the shell of the McIntyre allograft by providing it with discrete protrusions (teeth) having a triangular cross-section and formed perpendicular to the surface, as suggested by Brantigan, as doing so would provide means to secure the allograft in its desired position.

Claims 6 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntyre (US 4,950,296 A) in view of Brantigan (US 4,834,757 A) as applied to claims 4 and 35 above, and further in view of Wagner et al. (US 5,306,309 A). McIntyre and Brantigan teach the claimed invention except that the protrusions are pyramidal protrusions. Wagner et al. teach a spinal implant ("50" in figure 3) comprising pyramidal protrusions ("76" in figure 3). It would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to construct the protrusions of Brantigan such that they are pyramidal in shape, as suggested by Wagner et al., since applicant has not disclosed that such a shape solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a protrusion on an implant surface. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Claims 7 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntyre (US 4,950,296 A) in view of Brantigan (US 4,834,757 A) as applied to claims 4 and 35 above, and further in view of Steffee (US 5,071,437 A). McIntyre and Brantigan teach the claimed invention except that the protrusions are conical protrusions. Steffee teaches a spinal implant ("5" in figure 2) comprising conical protrusions ("28" in figure 2). It would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to construct the protrusions of Brantigan such that they are conical in shape, as suggested by Steffee, since applicant has not disclosed that such a shape solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a protrusion on an implant surface. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Claims 12 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntyre (US 4,950,296 A) in view of Brantigan (US 4,834,757 A) as applied to claims 1 and 32 above, and further in view of Wagner et al. (US 5,306,309 A), Grossman et al. ("The use of freeze-dried fibular allograft in anterior cervical fusion."), Kay et al. ("Total elbow allograft for twice-failed total elbow arthroplasty. A case report."), Cara et al. ("Iliac allograft used for sternal reconstruction after resection of a chondrosarcoma."), and Mnaymneh et al. ("Massive allografts in salvage revisions of failed total knee arthroplasties."). McIntyre and Brantigan teach the claimed invention except that the allograft is selected from tibial, fibular, humeral, and iliac material and the shape is selected from a group consisting of D-shape, dowel-shape, and ring shape.

McIntyre teach that the allograft can be ring-shaped ("28" in figure 4) or dowel-shaped ("12" in figure 1). Wagner et al. teach a spinal implant ("50" in figure 3) that is D-shaped. Mnaymneh et al. teach the use of a tibial allograft (abstract). Grossman et al. teach the use of a fibular allograft (abstract). Kay et al. teach the use of a humeral allograft (abstract). Cara et al. teach the use of an iliac allograft (abstract). It would have been obvious to one of ordinary skill in the art to select the allograft from tibial, fibular, humeral, and iliac material, as suggested by Mnaymneh et al., Grossman et al., Kay et al., and Cara et al., since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. It would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to construct the allograft of McIntyre such that it is D-shaped, dowel-shaped, or ring-shaped, as suggested by McIntyre and Wagner et al., since applicant has not disclosed that such a shape solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for an allograft depending on its intended use. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Claims 26 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntyre (US 4,950,296 A) in view of Brantigan (US 4,834,757 A) as applied to claims 1 and 32 above, and further in view of Grossman et al. ("The use of freeze-dried fibular allograft in anterior cervical fusion."), Kay et al. ("Total elbow allograft for twice-failed total elbow arthroplasty. A case report."), Cara et al. ("Iliac allograft used for

sternal reconstruction after resection of a chondrosarcoma.”), and Mnaymneh et al. (“Massive allografts in salvage revisions of failed total knee arthroplasties.”). McIntyre and Brantigan teach the claimed invention except that the allograft is selected from tibial, fibular, humeral, and iliac material. Mnaymneh et al. teach the use of a tibial allograft (abstract). Grossman et al. teach the use of a fibular allograft (abstract). Kay et al. teach the use of a humeral allograft (abstract). Cara et al. teach the use of an iliac allograft (abstract). It would have been obvious to one of ordinary skill in the art to select the allograft from tibial, fibular, humeral, and iliac material, as suggested by Mnaymneh et al., Grossman et al., Kay et al., and Cara et al., since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntyre (US 4,950,296 A) in view of Brantigan (US 4,834,757 A), Brantigan (US 4,878,915 A), Michelson (US 5,593,409 A), and Wagner et al. (US 5,306,309 A). McIntyre discloses a textured bone allograft (figures 1 and 2; column 2, line 22 through column 3, line 4). McIntyre fails to teach a plurality of spaced protrusions or any characteristics of those protrusions. Brantigan ('757) teaches a prosthetic fusion implant (“11” in figure 7) comprising a plurality of spaced protrusions (“22” in figure 7) wherein the protrusions are defined by teeth (“22” in figure 7) and grooves (“23” in figure 7). Brantigan ('915) teaches a prosthetic fusion implant (“11” in figure 6) comprising a plurality of spaced protrusions (“11b” in figure 6) wherein the protrusions are defined by

knurlings ("11b" in figure 6). Brantigan ('915) teaches a prosthetic fusion implant ("33" in figure 9) comprising a plurality of spaced protrusions ("33b" in figure 9) wherein the protrusions are defined by threads ("33b" in figure 9). Michelson teaches a spinal fusion implant ("100" in figure 3) comprising a plurality of spaced protrusions ("120" in figure 3) wherein the protrusions are defined by ratchetings ("120" in figure 3). Wagner et al. teach a spinal implant ("50" in figure 3) comprising a plurality of spaced protrusions ("76" in figure 3) wherein the protrusions are defined by a waffle pattern ("76" in figure 3). It would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to construct the protrusions of Brantigan such that they are defined by a structure selected from a waffle pattern, teeth, grooves, threads, knurlings, and ratchetings, as suggested by Brantigan ('757), Brantigan ('915), Michelson, and Wagner et al., since applicant has not disclosed that such shapes solve any stated problem or are anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a protrusion on an implant surface. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Response to Arguments

Applicant's arguments filed 4 December 2008 have been fully considered but they are not persuasive.

Regarding the 35 U.S.C. 112 rejections, Applicant points to paragraph 0074 of the specification and Figs. 7 and 8 and states that these provide dimensions of

protrusions in the form of threads from which the closeness of spacing of the threads can be discerned. The examiner respectfully points out that Applicant elected the species of Fig. 12 in the reply filed 19 March 2008. Thus, the claims are read in light of the species of Fig. 12, not the species of Figs. 7-8.

Regarding the 35 U.S.C. 103 rejections, Applicant has not provided any arguments regarding the merits of the rejections. As such, the examiner is upholding the rejections as made in the 30 May 2008 Office Action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-270-3815. The examiner can normally be reached on Mon. - Fri., until 2:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. N. H./
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733